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08/797,770	02/07/97	BAROFISKY	A 4430-18

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EXAMINER

PREBILIC, P

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 08/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/797,770

Applicant(s)

Barofsky et al

Examiner

Paul Prebilio

Group Art Unit

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☒ Responsive to communication(s) filed on Jun 9, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24, 36-55, 74, and 76-104 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24, 36-55, 74, and 76-104 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claim Objections

Claims 11, 14, 19, 100, and 103 are objected to because of the following informalities:

With regard to claims 11 and 14, they apparently have the same scope.

With regard to claim 14, it contains redundant and grammatically awkward language.

With regard to claim 19, "said cells" lacks antecedence.

With regard to claim 100, "tropoelastin biomaterial" lacks antecedence.

With regard to claim 103, last two lines, the last step of the method lacks an active step term such as "forming" or "applying". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 36-55, 74, 76-98, and 100-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to 24, 36-55, 74, 76,98, and 100-104, the terminology of "consisting essentially of" has a confusing and indefinite scope in that it apparently does not preclude crosslinking agents used to polymerize the tropoelastin (see page 8, line 21 to page 9, line 9 of the present specification), but it does, according the Applicant's argument, preclude fibrin and

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polypeptides; see the 37 CFR 1.132 declaration filed July 12, 1999. It is the Examiner's position that crosslinking agents, fibrin, and polypeptides are all material to the structure and that they would be precluded by "consisting essentially of" language. In view of the Applicant's specification, however, this terminology will be interpreted as having the same scope as "comprising".

With regard to claims 47-55 and 100, on line 3 of claim 47, it is unclear what the polymerizable monomer consists essentially of because no term follows this transitional phrase such that no element is provided by the providing step.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12, 13, 14, 16-22, 24, 74, and 76-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-14, and 16-35 of U.S. Patent No. 6,087,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets parallel each other in that the

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present claims set forth a biomaterial and the copending claims set forth an elastin biomaterial. However, since "biomaterial" is a broader more generic term than "elastin biomaterial" is it the Examiner's position that the present claim sets are obvious in view of each other.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24, 36-55, 74, 76-100, and 103-104 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014).

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Gregory et al is viewed as anticipating the present claims because crosslinked or polymerized tropoelastin is elastin even though it is not called such in the disclosure because the tropoelastin is uncrosslinked and unpolymerized precursor to elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al, especially Figure 1, page 1, lines 12-23 and page 8, line 21 to page 9, line 9. In other words, tropoelastin monomer is merely a precursor to elastin such that when tropoelastin is formed into a biomaterial by crosslinking or polymerization, it becomes elastin. Therefore, the term tropoelastin biomaterial, as defined in the present specification as crosslinked or polymerized tropoelastin, is actually elastin or elastin-based material. For these reasons, the claims are anticipated by Gregory et al (WO).

Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al on Col. 9, lines 1-26. Furthermore, it is prima facie obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

Claims 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's Admission wherein the claimed process of tropoelastin polymerization reads on the natural process of elastin formation in vertebrates according to Bedell-Hogan, et al in the Journal of Biological Chemistry; see page 1, lines 12-23 of the present specification.

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Claims 47, 48, and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Labroo et al (US 5,428,014) wherein the terminology "consisting essentially of" does not apparently preclude crosslinking agents to polymerize tropoelastin so it is the Examiner's position that it does not necessarily eliminate other polypeptides as disclosed by Labroo et al because these other polypeptides could be construed as crosslinking agents; see the whole document especially Col. 9, lines 1-21.

Allowable Subject Matter

Claims 101 and 102 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed June 9, 2000 have been fully considered but they are not persuasive.

Applicant argues that Section 2111.3 of the MPEP states that the phrase "consisting essentially of" is limited to materials that affect the basic a novel characteristics of the claimed invention. However, this phrase is used to include only small amounts of impurities, water, etc. and to preclude all else. Applicant, however, states that this phrase does not preclude cross-linking agents. Since crosslinking agents are actually necessary for the invention and reacted with the tropoelastin to polymerize it, it is not clear to the Examiner what consisting essentially of is

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intended to preclude. For this reason, "consisting essentially of" was interpreted as having the scope of "comprising".

In response to the traversal of the Gregory (WO) rejection that the 37 CFR 1.131 declaration overcomes the rejection, the Examiner posits that the declaration is insufficient to overcome the rejection for the reasons set forth below; particularly, the declaration fails to show that due diligence was present. In addition, it is noted that additional information has not been provided as Applicant stated he would provide.

The declaration filed on July 12, 1999 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gregory et al (WO 96/14807) reference.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Gregory et al (WO) reference to either a constructive reduction to practice or an actual reduction to practice. Specifically, there is no due diligence shown from the conception date before May 23, 1996 to the constructive reduction on February 7, 1997; see MPEP 715.07(a) which is incorporated herein by reference thereto. In fact, a period of 2 days lacking activity has been held to be fatal; see *In re Mulder* 219 USPQ 189, 193 (Fed. Cir. 1983).

In addition, the declaration provides very little evidence such that even conception of the claimed invention is not shown; see MPEP 715.02 which is incorporated herein by reference. For example, the declaration fails to disclose anything about radiation fusion, a tissue substrate, a support member, polymerization, or an energy absorbing material even each of the present claims

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set forth at least one of these limitations. For this reason, conception of the claimed invention is not adequately shown to the extent that this insufficiency alone renders the declaration defective.

In response to the traversal of the rejection of claims 47 and 48 based upon Applicant's admission, the Examiner maintains that the Applicant's admission in the specification is sufficient to read on the claimed invention such that the present claims are anticipated thereby. On lines 15 to 17, it states that elastin is formed by "the secretion and crosslinking of tropoelastin" in vertebrates. Therefore, the step of forming a biomaterial from tropoelastin is a naturally occurring process which the present claims are read on thereby.

In response to the traversal of Labroo et al, it is noted that claims 47, 48, and 53-55 are no longer limited to tropoelastin because the amendments thereto eliminated the terms "tropoelastin". For this reason, the argument against Labroo et al is not commensurate with the scope of the present claims. In addition, it is noted that the terminology "consisting essentially of" does not preclude any materials because it is not used in a manner consistent with its accepted meaning in present patent law.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilo
Primary Examiner
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